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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,389	03/12/2004	Mitsunori Ono	3211.1013-001	1892

21005 7590 06/21/2006

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EXAMINER

HABTE, KAHSAI

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/799,389		ONO ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Kahsay Habte		1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

**DETAILED ACTION**

1. Claims 1-28 are pending in this application.

***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-14 (in part) and 25-28 (in part), drawn to indolizines (i.e.  $V_1 = V_2 = V_3 = V_4 = C$ , see Ex. No. I-1 at page 28 of the specification), classified in class 546, subclass 121.
  - II. Claims 1-14 (in part) and 25-28 (in part), drawn to pyrrolo[1,2-b]pyridazines (i.e.  $V_1 = V_2 = V_3 = C$  and  $V_4 = N$ , see Ex. No. I-4 at page 28 of the specification), classified in class 544, subclass 235.
  - III. Claims 1-14 (in part) and 25-28 (in part), drawn to pyrrolo[1,2-c]pyrimidines (i.e.  $V_1 = V_2 = V_3 = C$  and  $V_4 = N$ , see Ex. No. I-9 at page 29 of the specification), classified in class 544, subclass 282.
  - IV. Claims 1-14 (in part) and 25-28 (in part), drawn to pyrrolo[2,1-b]thiazoles (see Ex. No. I-10 at page 29 of the specification), classified in class 548, subclass various.
  - V. Claims 1-14 (in part) and 25-28 (in part), drawn to pyrrolo[2,1-b]oxazoles (see Ex. No. I-11 at page 30 of the specification), classified in class 548, subclass various.
  - VI. Claims 1-14 (in part) and 25-28 (in part), drawn to pyrrolo[1,2-a]imidazoles (see Ex. No. I-14 at page 30 of the specification), classified in class 548, subclass various.

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- VII. Claims 1-14 (in part) and 25-28 (in part), drawn to others (e.g.  $V_3 = N$  and  $V_1-V_3 = C$ ), classified in class 544, 546, 548, subclass various.
- VIII. Claims 15-16, drawn to complex composition, classified in class 514, subclass various.
- IX. Claims 17-24, drawn to method of use, classified in class 514, subclass various.

The inventions are distinct, each from the other because of the following reasons:

Groups I-IX are directed to structurally dissimilar compounds such that the variable core created by the varying definitions of  $V_1-V_4$  in Formula (I) do not belong to the same recognized class of chemical compounds in the art, and references anticipating one invention, would not render obvious the others. Groups I-VII are drawn compounds, simple composition, are different from Group VIII that are drawn to complex composition. Group VIII has an additional ingredient (e.g. agent against cancer) that is not present in Group I. This is because of the possibility of synergistic interaction, which is usually the purpose of the complex composition in the first place. Groups I-III are drawn to a six-membered heterocyclic ring that is fused to another 5-membered heterocyclic ring and are different from Groups IV-VI that are drawn to two fused 5-membered heterocyclic rings. Group I is different from Groups II-III, since it is drawn to indolizines (one nitrogen atom in the bicyclic ring). Groups II-III have two nitrogen atoms in the bicyclic ring. Group II is different from Group III, since it is drawn to fused pyridazines (1,2-diazine). Group III is different from other groups, since it is drawn to fused pyrimidines (1,3-diazine). Group VII is drawn to others (core structures that don't

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fall into Groups I-VI) and is different from Groups I-VI. Inventions I-VII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case indolizines are used for the treatment of pain that is materially different process. Thus, separate searches in the literature as well as in the U.S. Patent Classification System would be required. Each group's compounds are made and used independently of each other and could support separate patents. The compounds differ significantly in chemical structures. One skilled in the art would not consider such diverse structure equivalents of each other.

### ***Advisory Rejoinder***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

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requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

If applicants elect Group IV, V, VI or VII; an election of a single disclosed species is required.

Because these inventions are distinct for the reasons given above and have acquired separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

A telephone call was made to Mr. Steven Davis on June 2, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

***Conclusion***

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kahsay Habte  
Primary Examiner  
Art Unit 1624


August 30, 2006

**Conclusion**

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

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Kahsay Habte  
Primary Examiner  
Art Unit 1624

June 15, 2006